

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 6 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS’ REPLY BRIEF IN SUPPORT OF MOTION TO EXCLUDE
CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter “Ethicon”) submit this reply brief in further support of their motion to exclude certain opinions of Bruce Rosenzweig, M.D.

I. The Court should preclude Dr. Rosenzweig from testifying about certain alleged complications associated with TVT Secur.

In their response, Plaintiffs represent that Dr. Rosenzweig stated certain things in his general report that he simply did not state. Dr. Rosenzweig’s opinions are not within the requisite degree of certainty and are not supported by reliable scientific evidence.

A. Opinions about the device’s fleece tips.

In his report, Dr. Rosenzweig simply does not opine to any degree of medical certainty that the TVT Secur’s ETHISORB® fleece tips lead to fixation issues. Instead, he plainly states that “Ethisorb **may** have also been a contributing factor to the fixation concern.” Ex. G to Def’s Motion, TVT Secur Gen. Report at 63, 76-77 (emphasis added). That is not enough. Because Dr. Rosenzweig is unwilling to testify that the fleece tips cause fixation issues—and, instead, only speculates as to whether they “may” cause problems—his opinion is inadmissible.

Even if Dr. Rosenzweig's opinion were sufficiently certain, it is not reliably supported by the medical literature. Plaintiffs claim that Dr. Rosenzweig "cited numerous publications and internal documents in his expert report" to support his opinion. Doc. 4977, pp. 3-4. But the publications cited in his expert report merely discuss data about TVT-Secur, generally, and do not discuss any testing or studies germane to the device's fleece tips. Although Plaintiffs specifically reference articles by Nambiar and Mostafa, those articles do not support any notion that Ethisorb caused fixation problems. *See* Ex. A & B hereto.

Plaintiffs also discuss testimony by Dr. Rosenzweig in which he referenced articles by "Hota (2012), Hamer (2012) and Krofta (2012)." Doc. 4977, p. 6. Not only are the Hamer and Krofta articles not referenced in Dr. Rosenzweig's report, Plaintiffs did not file those articles as exhibits or otherwise demonstrate how they support Dr. Rosenzweig's opinions about fleece tips. They do not.

The Hota article is filed as Exhibit I to Ethicon's motion. Therein, the authors merely stated that "[t]he TVT-S **may theoretically** migrate with time, detaching from the obturator internus muscle," that "excessive hydrodissection or sharp dissection of the periutlral space **may** affect the degree of attachment of the absorbable 'fleece' on either end of the TVT-S," and that "the attachment of the fleece **could** be compromised if a hematoma developed within the obturator internus muscle as a result of the surgical procedure." Ex. I to Def's Motion, Hota L., "TVT Secur (Hammock) Versus TVT-Obturator," *Female Pelvic Med. Reconstr. Surgery*, p. 44 (2012) (emphasis added). But there is no reference to any testing of these theoretical observations.

In short, Dr. Rosenzweig has merely stated that TVT Secur's fleece tips "may" be a problem based on an article or two that simply suggested that it "may" be a problem. This is far from the standard of scientific reliability that *Daubert* demands.

B. Opinions about the device's introducer.

Dr. Rosenzweig's opinions about TVT Secur's introducer are inadmissible for similar reasons. Once again, Plaintiffs ignore that Dr. Rosenzweig has not indicated that the introducer caused erosions, but instead, merely states that it "potentially" caused erosions. Ex. G to Def's Motion, TVT Secur Gen. Report at 63-64.

According to Plaintiffs, Dr. Rosenzweig's opinions are supported by "numerous medical/scientific articles." Doc 4977, p. 6. Yet, once again, Plaintiffs fail to identify these "numerous" articles. The only article referenced in Dr. Rosenzweig's report is the Hota article, which merely indicates that the introducer "potentially" causes problems but that the etiology is "unclear" without exploring the issue further. Ex. I to Def's Motion, Hota at 44.

Otherwise, Plaintiffs only reference testimony in which Dr. Rosenzweig mentions unidentified studies by "Lim and Hinoul." Doc 4977, p. 9. Tellingly, Plaintiffs do not attach those articles to their response to demonstrate that they truly support Dr. Rosenzweig's opinions about the introducer, nor do they even identify the names of the articles.¹ Instead, they ask the Court to merely take their and Dr. Rosenzweig's word for it that the articles support Dr. Rosenzweig's opinions.

Dr. Rosenzweig was required to provide support for his opinions in his report. He did not do so, and his opinions are unreliable.

¹ Dr. Rosenzweig did not claim that the Hinoul study even referenced the introducer. Although he claimed that the Lim study did so, that study is attached as makes **no reference** to TVT Secur's introducer. *See* Ex. C hereto, Lim, et al., "Short-term clinical and quality-of-life outcomes in women treated by the TVT-Secur procedure."

CONCLUSION

For the reasons set forth and referenced herein and in Ethicon's initial brief, Ethicon respectfully requests that the Court grant its Motion to Limit the Testimony of Bruce Rosenzweig, M.D.

Respectfully Submitted,

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I hereby certify that on this day I electronically filed the foregoing document with the Clerk of the Court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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